§170.315(a)(6) Problem list

2015 Edition CCGs

Version 1.1 Updated on 12-18-2015

Revision History		
Version #	**Description of Change**	**Version Date**
1.0	Initial Publication	10-22-2015
1.1	Added clarification that ONC-ATLs and ONC-ACBs have the discretion to offer streamlined testing for systems certified to the 2014 Edition problem list certification criterion.	12-18-2015

Regulation Text

Regulation Text

§170.315 (a)(6) *Problem list—*

Enable a user to record, change, and access a patient's active problem list:

(i) *Ambulatory setting only.* Over multiple encounters in accordance with, at a minimum, the version of the standard specified in §170.207(a)(4).

(ii) *Inpatient setting only.* For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in §170.207(a)(4).

Standard(s) Referenced

Applies to entire criterion

§ 170.207(a)(4) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), U.S. Edition, September 2015 Release

Certification Companion Guide: Problem list

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is <u>not</u> a substitute for the 2015 Edition final regulation. It extracts key portions of the rule's preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the 2015 Edition final rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

Link to Final Rule Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
Revised	No	Included	Yes

Certification Requirements

<u>Privacy and Security</u>: This certification criterion was adopted at § 170.315(a)(6). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(a) "paragraph (a)" criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (a) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be presented once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) "VDT" and (e)(2) "secure messaging," which are explicitly stated.

Table for Privacy and Security

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))
  - Auditable events and tamper-resistance (§ 170.315(d)(2))
  - Audit reports (§ 170.315(d)(3))
  - Amendments (§ 170.315(d)(4))
  - Automatic access time-out (§ 170.315(d)(5))
  - Emergency access (§ 170.315(d)(6))
  - End-user device encryption (§ 170.315(d)(7))
- If choosing Approach 2:
  - For each applicable P&S certification criterion not certified for approach 1, the health IT developer may certify for the criterion using system documentation which provides a clear description of how the external services necessary to meet the P&S criteria would be deployed and used. Please see the 2015 Edition final rule correction notice at 80 FR 76870 for additional clarification.

Design and Performance: The following design and performance certification criteria (adopted in §

170.315(g)) must also be certified in order for the product to be certified.

- Safety-enhanced design (§ 170.315(g)(3)) must be explicitly demonstrated for this criterion.
- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, the QMS' need to be identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively the developer must state that no accessibility-centered design was used.

Table for Design and Performance

- Safety-enhanced design (§ 170.315(g)(3))
- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- Health IT Modules can present for certification to a more recent version of SNOMED CT®, U.S. Edition than the September 2015 Release per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62620]
- We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.
  - The SNOMED CT® OID: 2.16.840.1.113883.6.96. [see also 80 FR 62612]
- We intend to offer efficient testing and certification processes (e.g., attestation) for Health IT Modules previously certified to the 2014 Edition problem list criterion for certification to this 2015 Edition problem list criterion. Please refer to the test procedure for this criterion. [see also 80 FR 62620]
- ONC-Authorized Testing Labs (ATLs) and ONC-Authorized Certification Bodies (ACBs) have the discretion to offer streamlined testing (e.g., attestation) to SNOMED CT® (U.S. Edition) for systems that have been certified to the 2014 Edition problem list certification criterion (§ 170.314(a)(5)).
- Health IT can use an interface that presents/displays local terms to a user in lieu of SNOMED CT® as long as the health IT system records the semantic representation of the problem list in SNOMED CT®. [see also 77 FR 54210]

Paragraph (a)(6)(i)

Technical outcome – For the ambulatory setting, a user can record, change, and access a patient's active

problem list over multiple encounters using the September 2015 Release of SNOMED CT® (U.S. Edition).

Clarifications:

- No additional clarifications available.

Paragraph (a)(6)(ii)

Technical outcome – For the inpatient setting, a user can record, change, and access a patient's active problem list for the duration of an entire hospitalization using the September 2015 Release of SNOMED CT® (U.S. Edition).

Clarifications:
- No additional clarifications available.

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